



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

October 7, 2004

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 74986-U / Micro Clean Alpha  
DP Barcode: D305845

To: Emily Mitchell, PM 32 / Wanda Mitchell  
Regulatory Management Branch  
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *Ian Blackwell*  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader *Karen Hicks 10/7/04*  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

Applicant: Selective Micro Technologies, LLC

FORMULATION FROM LABEL:

Active Ingredient(s):

Sodium chlorite

Other Ingredient(s):

% by wt.

30.5

69.5

Total: 100%

- I BACKGROUND: Selective Micro Technologies, LLC, has submitted a package of information to support the acute toxicity requirements of their product, "Selective Micro Clean Alpha". This submission cites four acute toxicity studies conducted on Registration Number 74986-1. The MRIDs of those studies are 457782-04 through 457782-07.

The registrant also requests the waiver of the acute inhalation toxicity and dermal sensitization studies for this product. The registrant wants waivers of these two studies based on the premise that this product is similar in formulation to Registration Number 74986-1.

II RECOMMENDATIONS: PSB findings are:

- 1 CTT/PSB/AD will allow the registrant to reference the primary eye irritation study conducted on 74986-1, along with a consideration of the pH of 74986-U. File Symbol 74986-U is assigned toxicity category I for primary eye irritation.
- 2 The request to cite the acute oral toxicity, acute dermal toxicity, and primary skin irritation studies (MRID Numbers 457782-04, 457782-05, and 457782-07) conducted on 74986-1 is denied. CTT/PSB does not feel that the formulations of the two products are similar enough for the two products to be considered substantially similar, or, to bridge the data from these three studies to support 74986-U. CTT/PSB notes that 74986-1 contains 13.45% active ingredient, while 74986-U contains 30.45% of that same active.
- 3 The waiver of the acute inhalation toxicity study is denied. The registrant will have to present data specific to 74986-U in order to have this product reconsidered for a waiver of the acute inhalation toxicity study.
- 4 The waiver of the dermal sensitization study is denied. The registrant will have to present data or other rationale specific to 74986-U in order to have a waiver of the dermal sensitization study reconsidered.

The acute toxicity profile for File Symbol 74986-U is currently:			
Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	none		Data Gap
Acute Dermal Toxicity	none		Data Gap
Acute Inhalation Toxicity	none		Data Gap
Primary Eye Irritation	457782-06	I	Cited
Primary Skin Irritation	none		Data Gap
Dermal Sensitization	none		Data Gap

### III LABELING:

- 1 The signal word will be "DANGER", based upon the toxicity category I classification of the primary eye irritation hazard.
- 2 No other precautionary labeling can be recommended for File Symbol 74986-U at this time.